

Attachment 13

AMENDED IN ASSEMBLY JUNE 15, 2005

AMENDED IN SENATE MAY 4, 2005

AMENDED IN SENATE APRIL 12, 2005

AMENDED IN SENATE APRIL 4, 2005

SENATE BILL

No. 401

Introduced by Senator Ortiz

February 17, 2005

An act to amend Section 56.05 of the Civil Code, relating to medical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 401, as amended, Ortiz. Medical information: pharmacies: marketing.

Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and, if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor. Existing law provides that this prohibition also applies to the marketing of medical information, as defined, excluding from that definition, for these purposes, communications for which the communicator does not receive remuneration from a 3rd party or for specified descriptive purposes, or that are tailored to the circumstances of a particular individual, as specified.

This bill would further provide that marketing includes a written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by, a manufacturer, labeler, or distributor of prescription drugs, except as specified. Because a violation thereof may be punishable as a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 56.05 of the Civil Code is amended to
2 read:

3 56.05. For purposes of this part:

4 (a) "Authorization" means permission granted in accordance
5 with Section 56.11 or 56.21 for the disclosure of medical
6 information.

7 (b) "Authorized recipient" means any person who is
8 authorized to receive medical information pursuant to Section
9 56.10 or 56.20.

10 (c) "Contractor" means any person or entity that is a medical
11 group, independent practice association, pharmaceutical benefits
12 manager, or a medical service organization and is not a health
13 care service plan or provider of health care. "Contractor" does
14 not include insurance institutions as defined in subdivision (k) of
15 Section 791.02 of the Insurance Code or pharmaceutical benefits
16 managers licensed pursuant to the Knox-Keene Health Care
17 Service Plan Act of 1975 (Chapter 2.2 (commencing with
18 Section 1340) of Division 2 of the Health and Safety Code).

19 (d) "Health care service plan" means any entity regulated
20 pursuant to the Knox-Keene Health Care Service Plan Act of
21 1975 (Chapter 2.2 (commencing with Section 1340) of Division
22 2 of the Health and Safety Code).

1 (e) “Licensed health care professional” means any person
2 licensed or certified pursuant to Division 2 (commencing with
3 Section 500) of the Business and Professions Code, the
4 Osteopathic Initiative Act or the Chiropractic Initiative Act, or
5 Division 2.5 (commencing with Section 1797) of the Health and
6 Safety Code.

7 (f) (1) “Marketing” means to make a communication about a
8 product or service that encourages recipients of the
9 communication to purchase or use the product or service.

10 (2) “Marketing” does not include any of the following:

11 (A) Communications made orally or in writing for which the
12 communicator does not receive direct or indirect remuneration,
13 including, but not limited to, gifts, fees, payments, subsidies, or
14 other economic benefits, from a third party for making the
15 communication.

16 (B) Communications made to current enrollees solely for the
17 purpose of describing a provider’s participation in an existing
18 health care provider network or health plan network of a
19 Knox-Keene licensed health plan to which the enrollees already
20 subscribe; communications made to current enrollees solely for
21 the purpose of describing if, and the extent to which, a product or
22 service, or payment for a product or service, is provided by a
23 provider, contractor, or plan or included in a plan of benefits of a
24 Knox-Keene licensed health plan to which the enrollees already
25 subscribe; or communications made to plan enrollees describing
26 the availability of more cost-effective pharmaceuticals.

27 (C) Communications that are tailored to the circumstances of a
28 particular individual to educate or advise the individual about
29 treatment options, and otherwise maintain the individual’s
30 adherence to a prescribed course of medical treatment, as
31 provided in Section 1399.901 of the Health and Safety Code, for
32 a chronic and seriously debilitating or life-threatening condition
33 as defined in subdivisions (d) and (e) of Section 1367.21 of the
34 Health and Safety Code, if the health care provider, contractor, or
35 health plan receives direct or indirect remuneration, including,
36 but not limited to, gifts, fees, payments, subsidies, or other
37 economic benefits, from a third party for making the
38 communication, if all of the following apply:

39 (i) The individual receiving the communication is notified in
40 the communication in typeface no smaller than 14-point type of

1 the fact that the provider, contractor, or health plan has been
2 remunerated and the source of the remuneration.

3 (ii) The individual is provided the opportunity to opt out of
4 receiving future remunerated communications.

5 (iii) The communication contains instructions in typeface no
6 smaller than 14-point type describing how the individual can opt
7 out of receiving further communications by calling a toll-free
8 telephone number of the health care provider, contractor, or
9 health plan making the remunerated communications. No further
10 communication may be made to an individual who has opted out
11 after 30 calendar days from the date the individual makes the opt
12 out request.

13 (3) ~~“Marketing”~~ *Notwithstanding any other provision of law,*
14 *“marketing”* includes a written communication that is provided
15 to a pharmacy patient by a pharmacist or by pharmacy personnel,
16 in conjunction with the dispensing of a prescription drug or
17 prescribed treatment therapy, that includes the trade name or
18 commercial slogan for any prescription drug, prescribed
19 treatment therapy, or over-the-counter medication other than the
20 prescription drug or prescribed treatment therapy being
21 dispensed, if the communication is paid for or sponsored, directly
22 or indirectly, by a manufacturer, labeler, or distributor of
23 prescription drugs. This paragraph shall not apply when a trade
24 name or commercial slogan for a prescription drug, prescribed
25 treatment therapy, or over-the-counter medication is included in
26 a written communication for the sole purpose of ~~identifying a~~
27 ~~potential adverse drug interaction with the prescription drug or~~
28 ~~prescribed treatment therapy being dispensed.~~ *providing*
29 *information about drug interactions, reported or potential*
30 *adverse events, or any other information necessary to ensure the*
31 *health and safety of the patient, or is part of a package insert that*
32 *has been approved by the federal Food and Drug Administration*
33 *to be distributed together with a prescription drug.*

34 (g) “Medical information” means any individually identifiable
35 information, in electronic or physical form, in possession of or
36 derived from a provider of health care, health care service plan,
37 pharmaceutical company, or contractor regarding a patient’s
38 medical history, mental or physical condition, or treatment.
39 “Individually identifiable” means that the medical information
40 includes or contains any element of personal identifying

1 information sufficient to allow identification of the individual,
2 such as the patient's name, address, electronic mail address,
3 telephone number, or social security number, or other
4 information that, alone or in combination with other publicly
5 available information, reveals the individual's identity.

6 (h) "Patient" means any natural person, whether or not still
7 living, who received health care services from a provider of
8 health care and to whom medical information pertains.

9 (i) "Pharmaceutical company" means any company or
10 business, or an agent or representative thereof, that manufactures,
11 sells, or distributes pharmaceuticals, medications, or prescription
12 drugs. "Pharmaceutical company" does not include a
13 pharmaceutical benefits manager, as included in subdivision (c),
14 or a provider of health care.

15 (j) "Provider of health care" means any person licensed or
16 certified pursuant to Division 2 (commencing with Section 500)
17 of the Business and Professions Code; any person licensed
18 pursuant to the Osteopathic Initiative Act or the Chiropractic
19 Initiative Act; any person certified pursuant to Division 2.5
20 (commencing with Section 1797) of the Health and Safety Code;
21 any clinic, health dispensary, or health facility licensed pursuant
22 to Division 2 (commencing with Section 1200) of the Health and
23 Safety Code. "Provider of health care" does not include
24 insurance institutions as defined in subdivision (k) of Section
25 791.02 of the Insurance Code.

26 SEC. 2. No reimbursement is required by this act pursuant to
27 Section 6 of Article XIII B of the California Constitution because
28 the only costs that may be incurred by a local agency or school
29 district will be incurred because this act creates a new crime or
30 infraction, eliminates a crime or infraction, or changes the
31 penalty for a crime or infraction, within the meaning of Section
32 17556 of the Government Code, or changes the definition of a
33 crime within the meaning of Section 6 of Article XIII B of the
34 California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: SB 401

VERSION: AMENDED JUNE 15, 2005

AUTHOR: ORTIZ

**SPONSOR: CA. PUBLIC INTEREST
RESEARCH GROUP**

RECOMMENDED POSITION: OPPOSE UNLESS AMENDED

SUBJECT: MEDICAL INFORMATION: PHARMACIES: MARKETING

Existing Law:

- 1) Defines marketing as "communication about a product or service that encourages recipients of the communication to purchase or use the product or service."
- 2) Excludes the following from the definition of marketing:
 - a. Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration from a third party for making the communication.
 - b. Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe
 - c. Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment for a chronic and seriously debilitating or life-threatening condition, if the health care provider, contractor, or health plan receives direct or indirect remuneration from a third party for making the communication, if all of the following apply:
 - i. The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.
 - ii. The individual is provided the opportunity to opt out of receiving future remunerated communications.
 - iii. The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications.

(Civil Code 56.05)

This Bill:

- 1) Defines "marketing" to include a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug or prescribed treatment therapy, that includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription drug or prescribed treatment therapy being dispensed, if the:
 - i. The communication describes includes the name of, or describes biochemical, pharmacological, or other scientific or health information for, any other drug or treatment other than the drug or treatment being dispensed; and
 - ii. The communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs.
- 2) Specifies that this definition does not apply when a trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or over-the-counter medication is included in a written communication for the sole purpose of providing information about drug interactions, reported or potential adverse events, or any other information necessary to ensure the health and safety of the patient, or is part of a package insert that has been approved by the federal Food and Drug Administration to be distributed together with a prescription drug.

(Civil Code 56.05 Amended)

Comment:

1) Author's Intent. The author's intent is to close a loophole that she sees in the law that allows drug manufacturers to distribute biased written information to patients through pharmacists during face-to-face drug consultations. An example would be an pharmacist giving a patient an advertisement, during the face to face consultation, that list other possible drugs that could be taken for the same condition.

2) Amendments. 1) Allow a patient the ability to opt out of receiving paid advertisements with their medications. 2) Required paid advertisement to be labeled as such and identify the sponsor of the advertisement.

3) Background. AB 715 (Chan, Chapter 562, Statutes of 2003), sought to prohibit marketing practices where a health care provider or entity was paid to market a third party's product or service to a patient, using that patient's medical information. While the bill protected consumer privacy, it did not completely deal with issues surrounding third party marketing to consumers. The question arises, does permitting drug companies to pay for advertising or the production of fact sheets used by pharmacists in consultations with patients benefit or harm the consumer?

AB 746 (Mathews, 2003) was proposed as "clean-up" legislation to AB 715. AB 746 would have clarified that pharmacists had the right to provide patient pamphlets with drug manufacture advertising or messages that informed patients of about the drug they were receiving. Pharmacists argued that including advertisements helped pay for the costs of producing the pamphlets and that prohibiting advertising would result in patients receiving less information about the drug they are taking. AB 746 died in the Senate.

Likewise, SB 401 is also being proposed as "clean-up" legislation to AB 715, but unlike AB 746, it takes the position that marketing information from drug manufacturers during face-to-face interaction is bad for the consumer and should therefore be prohibited. Supporters of the measure argue that information from pharmacists should be free from bias and information from drug manufacturers may confuse patients and contradict the information they receive from their doctor.

4) Previous Legislation.

AB 715 (Chan, Chapter 562, Statutes of 2003) Personal Information.

AB 746 (2003) Medical Information: Pharmacies, Marketing; this measure died in the Senate.

5) Support & Opposition

Support: California Public Interest Research Group (sponsor)
California Alliance for Retired Americans
California Labor Federation
Consumers Union

Opposition: The Body
CA Pharmacists Association
CA Retailers Association
Catalina Health Resource; Kaiser Permanente
Nat'l Association of Chain Drug Stores
Nat'l Consumers League
Nat'l Council on Patient Information and Education
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America
Rite Aid

6) History.

2005

June 28 Set, first hearing. Hearing canceled at the request of author.

June 15 From committee with author's amendments. Read second time. Amended. Re-referred to committee.

June 13 To Coms. on HEALTH and JUD.

May 26 In Assembly. Read first time. Held at Desk.

May 26 Read third time. Passed. (Ayes 23. Noes 13. Page 1190.) To Assembly.

May 25 Read second time. To third reading.

May 24 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.

May 16 Set for hearing May 23.

May 4 Read second time. Amended. Re-referred to Com. on APPR.

May 3 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 5. Noes 2. Page 801.)

Apr. 14 Set for hearing April 26.

Apr. 12 Read second time. Amended. Re-referred to Com. on JUD.

Apr. 11 From committee: Do pass as amended, but first amend, and re-refer to Com. on JUD. (Ayes 8. Noes 3. Page 498.)

Apr. 4 From committee with author's amendments. Read second time. Amended. Re-referred to committee.

Mar. 16 Set for hearing April 6.

Feb. 24 To Coms. on HEALTH and JUD.

Feb. 18 From print. May be acted upon on or after March 20.

Feb. 17 Introduced. Read first time. To Com. on RLS. for assignment. To print.

SB 401

As Amended: June 15, 2005

ASSEMBLY COMMITTEE ON HEALTH

Wilma Chan, Chair

SB 401 (Ortiz) -

SUBJECT: Medical information: pharmacies: marketing.

SUMMARY : Includes in the definition of "marketing," under the Confidentiality of Medical Information Act (CMIA), written communications, which pharmacists provide to patients when dispensing prescription drugs, if the communication includes the trade name or commercial slogan for any drug other than the dispensed drug when the cost of the communication is paid, directly or indirectly, by a drug manufacturer or distributor. Specifically, this bill :

- 1) Defines "marketing," for purposes of the CMIA, to include a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug or prescribed treatment therapy, that includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication, other than the prescription drug or prescribed treatment therapy being dispensed, if the communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs.
- 2) States the provisions of #1) above do not apply when a trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or over-the-counter medication is included in a written communication for the sole purpose of providing information about drug interactions, reported or potential adverse events, or any other information necessary to ensure the health and safety of the patient, or is part of a package insert that has been approved by the federal Food and Drug Administration (FDA) to be distributed together with a prescription drug.

EXISTING LAW :

- 1) Establishes the CMIA which prohibits any provider of health care, health care service plan, contractor, or corporation from intentionally using any medical information, as defined, for any purpose not necessary to provide health care services to the patient, except as expressly authorized by the patient, or as otherwise required or authorized by law.
- 2) Defines "marketing," for the purposes of the CMIA, as making a

communication about a product or service that encourages recipients of the communication to purchase or use the product or service. Excludes from the definition of marketing the following:

- a) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration;
 - b) Communications made to current enrollees of a health care service plan for purposes related to payment for a product or service, describing plan benefits or services, or describing the availability of more cost effective pharmaceuticals; and,
 - c) Communications that are tailored to the circumstances of a particular individual who is in a disease management program for a chronic and seriously debilitating or life threatening condition, even if the health care provider receives direct or indirect remuneration, if the individual receiving the communication is notified in at least 14-point type that the provider has been remunerated, the source of that remuneration, and that the patient has the opportunity to opt out of receiving future remunerated communications.
- 3) Establishes, under federal law, the FDA to regulate the manufacture, labeling, sale, and distribution of drugs in the United States. Requires the FDA, before any other initiatives can be proposed, to evaluate the success of a public-private action plan with a goal that useful written information be given to at least 75% of persons receiving new prescriptions by the year 2000 and 95 percent by 2006
- 4) Under the federal Health Insurance Portability and Accountability Act (HIPAA), provides a federal floor of protections for protected medical information and permits states to enact greater protections.

FISCAL EFFECT : Unknown. This bill was approved by the Senate Appropriations Committee pursuant to Senate Rule 28.8.

COMMENTS :

1) PURPOSE OF THIS BILL . According to the author, this bill is needed because consumers rely on their pharmacists for accurate, unbiased information. Information received from pharmacists should be objective and free from advertisements that are specifically designed to build name recognition. The author believes that injecting direct to consumer

advertisements within these communications is wholly inappropriate and can be mistaken as a tacit endorsement of a particular product or drug or an implicit veto of a physician's recommended course of treatment. This is particularly egregious given that patients receive these advertisements after their physicians have examined them and prescribed the most appropriate treatment in their professional opinion. The author states that physicians, not drug manufacturers, should be a patient's best resource in determining the most appropriate and cost effective course of treatment to meet their health needs, and that this bill will ensure that pharmacy communications are not used as yet another vehicle to steer consumers to unnecessary and high-priced prescription drugs. Finally, the author notes that studies show that direct to consumer advertising is a key contributor to the rising costs of prescription drugs. Additionally, these types of advertisements can interfere with the doctor-patient relationship by leading patients to self diagnose and demand specific brand name drugs and treatments. According to the author, written communications that generally inform patients to consult their physicians about whether alternative drugs or other, treatments may be beneficial to them without promoting a specific drug will facilitate better patient-physician dialogue and lead to more appropriate prescribing.

2)BACKGROUND . In response to the growing practice of third-party companies paying health care providers to market products or services to patients using the patients' medical information, the California State Office of HIPAA Implementation and the California Medical Association jointly sponsored AB 715 (Chan), Chapter 562, Statutes of 2003, to address improper use medical information. AB 715 amended existing provisions of the CMIA to prohibit the use or sharing of medical information without patient authorization, and specified that a health care provider could not use medical information for marketing purposes without authorization, with certain exceptions. AB 746 (Matthews) of 2004 attempted to create additional exceptions to AB 715's definition of "marketing" by specifying that written communications provided to a pharmacy patient during a face-to-face interaction with the pharmacist were not "marketing" so long as: a) the communication helped pharmacists meet specified federal information distribution requirements; b) the majority of the communication related to the drug being dispensed; c) the pharmacist was available to answer questions; d) specific identifying information was not used to determine the sponsored content; and, e) any sponsored information was clearly labeled as such. AB 746 died on the Senate floor after opponents argued that it would be inappropriate for pharmacists to include advertisements in what should be

unbiased information packets.

3)HIPAA . HIPAA was primarily enacted in 1996 to improve health insurance access for persons changing employers or leaving the workforce, but also contained administrative simplification provisions and medical information privacy standards. In 2002, pursuant to a HIPAA requirement, the U.S. Department of Health and Human Services (HHS) published it's "Standards for Privacy of Individually Identifiable Health Information: Final Rule" (Standards) in the federal register. Under the Standards, in most cases, a health care provider or health plan must first obtain an authorization from the patient for any use or disclosure of protected health information for marketing. Under the Standards, marketing information is defined to include situations where a health care provider or health plan discloses protected health information to another entity in exchange for direct or indirect remuneration so that the other entity can make a communication about its own product or services to the patients of the provider or plan. In some cases, such as those addressed in AB 715 and in this bill, information is not disclosed to the third party, yet marketing still occurs. Under HIPAA, this marketing is permissible without patient authorization. However, HIPAA is only a floor, and states may enact greater privacy protections.

4)PHARMACY COMMUNICATIONS . Current state and federal law requires drug manufacturers to provide, and pharmacists to distribute, written communications, commonly referred to as "patient drug information leaflets" or "patient package inserts" to consumers with certain prescription drugs. This information generally contains objective health information related to the appropriate dosage, potential side effects, drug interactions, and other information relevant to the prescribed medication. Although not required for most prescriptions, most pharmacies include information leaflets with all prescriptions they dispense. Some pharmacists' written communications additionally include direct to consumer advertisements for competing or adjunctive drugs and treatment therapies other than the medication the patient's physician has prescribed. Drug manufacturers pay third party companies to have their advertisements included in a "newsletter" which is then provided to pharmacy patients when their prescriptions are filled. The pharmacist enters the patient's gender, drug, and age into a software program which will then generate a threefold pamphlet containing specified utilization and safety information as required by state and federal law, health tips from federal and state agencies or private health organizations, and targeted direct to consumer advertisements for alternative or adjunctive medications based on the information provided. The third party company provides the

pharmacy with the software and paper free of charge.

One of the major companies providing these newsletters is Catalina Health Resource (CHR), a subsidiary of Catalina Marketing. CHR provided materials to the committee describing its PatientLink newsletters. According to CHR, PatientLink is the nation's leading newsletter that provides customized health care information for patients. Each month one hundred million patients receive a PatientLink newsletter when picking up their prescriptions. CHR states that less than one in four PatientLink newsletters contain sponsored messaging, which is always or almost always clearly disclosed. According to CHR's website, 19 of the top 20 pharmaceutical companies use PatientLink and the company's network includes more than 15,000 pharmacy outlets. The website includes a demonstration of how PatientLink can help encourage patients to switch from one drug to another and claims that drug companies using PatientLink on average experience a prescription volume gain of 8.1% and a return on investment of greater than three to one.

5)SUPPORT . Supporters argue that pharmacists are regarded as the most trusted health care professional and contend that such communications this bill seeks to ban could be mistaken as a tacit endorsement of a particular drug or an implicit veto of a physician's recommended course of treatment. Supporters believe that patients have a reasonable expectation that the information they receive from the pharmacy is objective. They insist that inserting paid advertising into the pharmacist-patient interaction betrays that expectation and changes the role of the pharmacist from unbiased information provider to drug company salesperson. They believe people take very seriously what is placed in prescription bags, believing important information is contained for them as patients. Supporters argue that this kind of advertising can undermine consumer confidence in the essential scientific information about dosage, side effects, and potential drug interactions that patients do need to receive from their pharmacists. Supporters also believe that since this advertising may conflict with a doctor's instructions for other prescriptions, it can also create a great deal of confusion for elderly patients, the chronically ill, or those with a large number of prescriptions. Supporters argue that drug safety concerns call for increased caution in expanding prescription drug marketing. They cite the recent highly publicized recall of the popular painkiller Vioxx, which they insist affected far more consumers than it should have due to aggressive direct-to-consumer advertising.

6)OPPOSITION . Opponents argue that this bill will interfere

with the distribution of valuable information to the detriment of patients. They believe consumers should receive as much information as possible about their conditions, their prescription drugs and treatment alternatives, including compliance and persistence messaging, disease state management materials, and information about alternative or adjunctive therapies. They report that pharmaceutical manufacturers often underwrite the costs of many of these written in-pharmacy communications. Rite Aid argues that most pharmacies find it financially necessary to contract with a third party company to prepare and format the material included in a customer insert because there are thousands of drugs that require background information and information related to these drugs is updated on a regular basis. Because of the significant expense of providing this information,

pharmacies often turn to drug manufacturers to sponsor these communications. Opponents argue that in evaluating sponsored patient communications, the focus should be on the value of the content and not on whether some part of the message has been sponsored. A number of HIV-AIDS organizations argue that this bill will severely restrict the free flow of useful health care information that is now available free of cost with every prescribed medication. Opponents state that pharmacies have experienced significant cuts in their reimbursement rates from the state's Medi-Cal program, workers' compensation and private payers, while paying increasingly more for prescription drugs. They believe this bill represents another operating cost that would have to be shouldered by pharmacies whose margins are already tightly constrained. Finally, opponents argue that this bill is contrary to HIPAA privacy regulations which state that refill reminders and information about treatment options are part of the patient's treatment, and that patients are considered to have consent to by filling the original prescription.

7)CONCERNS AND PROPOSED AMENDMENTS . The National Council on Patient Information and the National Consumers League (NCL) are concerned that this bill will impede the flow of useful medicine information to consumers. Both organizations refer to NCL's ten best practice principles for health care communications provided by pharmacies as standards that protect patients. Among those 10 principles are identifying sponsorship and providing patients with an opportunity to opt out. NCL and La Clinica expressly request the bill be amended to allow sponsored pharmacy communications if sponsorship identification and opt-out provisions are included. Opponents of this bill, prior to its passage in the Senate, proposed an amendment to require clear disclosure of sponsorship. The AIDS Legal Referral Panel and the California Hispanic Health Care Association express concerns that this bill will preclude

patients from receiving important information.

8)LEGISLATIVE COUNSEL OPINION . The author has requested an opinion from Legislative Counsel asking if this bill in any way would prohibit individuals with chronic and seriously debilitating or life-threatening conditions, such as HIV-AIDS, from receiving information about alternative treatment options.

9)QUESTIONS AND COMMENTS . This bill addresses issues at the intersection of health care information, medical privacy, and pharmaceutical marketing and raises the following questions: Do patients have a right to receive this information without accompanying marketing messages from third parties (generally other drug companies)? Should pharmacies be expected to pay for this material? Aren't consumers now paying for these communications in the prices that consumers, employers, and government are paying for prescription drugs? How often are the "advertised" alternative drugs included in the communication a more expensive brand-name drug that is being suggested to replace a less expensive generic?

10)DOUBLE REFERRAL . This bill has been double-referred. Should this bill pass out of this committee, it will be referred to the Assembly Judiciary Committee.

REGISTERED SUPPORT / OPPOSITION :

Support

California Public Interest Research Group (sponsor)
California Alliance for Retired Americans
California Dialysis Council
California Labor Federation
Consumers Union
Gray Panthers
Greenlining Institute
Latino Coalition for a Healthy California

Opposition

AIDS Emergency Fund
Bay Area Young Positives
Black AIDS Institute
California Pharmacists Association
California Retailers Association
Catalina Health Resource
MAGNET
National Association of Chain Drug Stores
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America

Rite Aid
San Francisco Kaiser HIV/AIDS Advisory Board
Shanti
Stop AIDS Project San Francisco
TheBody.com
2 individuals

Analysis Prepared by : John Gilman / HEALTH / (916) 319-2097

Attachment 14

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AMENDED IN SENATE JUNE 30, 2005

AMENDED IN SENATE JUNE 15, 2005

Senate Concurrent Resolution

No. 49

Introduced by Senator Speier

May 17, 2005

Senate Concurrent Resolution No. 49—Relative to medication errors.

LEGISLATIVE COUNSEL'S DIGEST

SCR 49, as amended, Speier. Medication errors panel.

This measure would create a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The measure would require the panel to convene by October 1, 2005, and to submit to the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006.

Fiscal committee: no.

1 WHEREAS, Numerous studies establish that medication errors
2 cause injury and death to patients and consumers; and

3 WHEREAS, The Institute of Medicine estimates the cost for
4 treatment of drug-related morbidity and mortality may run nearly
5 \$77 billion a year nationally; and

6 WHEREAS, Research demonstrates that most injuries
7 resulting from medication errors are not the fault of any
8 individual health care professional, but rather represent the
9 failure of a complex health care system; and

10 WHEREAS, The Federal Food and Drug—Agency
11 *Administration* has approved 122 chemical compounds since

1 2002, and over 17,000 existing trade and generic names of
2 products exist, many of which sound alike or are spelled alike;
3 and

4 WHEREAS, These products are also packaged and distributed
5 in similar shapes and forms; and

6 WHEREAS, The demand for prescription drugs is expected to
7 substantially increase; and

8 WHEREAS, Medication errors occur in all settings in which
9 prescription drug products are prescribed, dispensed, furnished,
10 ordered, or otherwise provided; and

11 WHEREAS, Many factors contribute to a poor understanding
12 by many consumers and patients about their prescriptions,
13 including frequent switching of generic brands that are each
14 different colors and shapes so that the same drug looks different
15 and confuses the patient making it hard to easily spot mistakes;
16 overworked pharmacists; reduced time with physicians for
17 patients to be given important drug information; patients seeing
18 multiple physicians that may be unaware of each other's care
19 plans; patients often using vitamins, herbs, and over-the-counter
20 drugs that can react with the medications they take and that both
21 the physician and pharmacist do not know about; and

22 WHEREAS, Research has demonstrated that improved
23 communication between patients and their health professionals is
24 the most effective means of reducing errors and drug
25 misadventures and improving health care outcomes; now,
26 therefore, be it

27 *Resolved by the Senate of the State of California, the Assembly*
28 *thereof concurring*, That a special panel be formed to study
29 causes of medication errors; and be it further

30 *Resolved*, That the Legislature shall convene the panel no later
31 than October 1, 2005; and be it further

32 *Resolved*, That the panel shall recommend improvements,
33 additions, or changes to be constructed and implemented for the
34 significant improvement of the health care system by reducing
35 errors associated with the delivery of prescription and
36 over-the-counter medications to consumers; and be it further

37 *Resolved*, That the panel membership shall consist of
38 appointees of the Senate Committee on Health; *and* the
39 Assembly Committee on Health; and be it further

1 *Resolved*, That the Speaker of the Assembly shall appoint to
2 the panel a member of the faculty of a school of pharmacy, a
3 representative of the California Pharmacists Association, a
4 representative of the California Association of Health Plans, a
5 representative of the Pharmaceutical Research and Manufacturers
6 of America, a member of the California Medical Association, a
7 member or representative of the Assembly Republican Caucus,
8 and a consumer representative; and be it further

9 *Resolved*, That the Senate Committee on Rules shall designate
10 the chair and appoint to the panel a representative of the
11 California Retailers Association Chain Drug Committee, a
12 member of the California Society of Hospital Pharmacists, a
13 representative of the Generic Pharmaceutical Association, a
14 representative of a public health organization, a member of the
15 California Nurses Association, a representative of the American
16 Association of Retired People, *a representative of the Consumer*
17 *Health Care Products Association*, and a member or
18 representative of the Senate Republican Caucus; and be it further

19 *Resolved*, That the members of the panel shall not receive
20 compensation, but shall be reimbursed from private sources for
21 necessary travel expenses for the purpose of attending meetings
22 of the panel, including any public meetings that the panel
23 schedules; and be it further

24 *Resolved*, That the panel shall submit to the Senate Committee
25 on Health a preliminary report of its conclusions and
26 recommendations by March 1, 2006, and a final report of its
27 conclusions and recommendations no later than June 1, 2006;
28 and be it further

29 *Resolved*, That the Secretary of the Senate transmit copies of
30 this resolution to the author for appropriate distribution.

Blank

SCR 49

As Amended: June 15, 2005

SENATE HEALTH

COMMITTEE ANALYSIS
Senator Deborah V. Ortiz, Chair

FISCAL: Non-Fiscal
4

9
CONSULTANT:
Margolis / ag

SUBJECT

Medication errors: creation of legislative panel

SUMMARY

This resolution makes findings related to the dangers and causes of medication errors, and resolves that a special panel be formed by the California Legislature to study the causes of medication errors and submit a final report to the Senate Committee on Health by June 1, 2006.

ABSTRACT

Existing law:

- 1.Requires every pharmacy to establish a quality assurance program that documents medication errors attributable to the pharmacy or its personnel.

This bill:

Includes the following findings:

- 1.Numerous studies establish that medication errors cause injury and death.
- 2.The Institute of Medicine estimates annual drug-related morbidity and mortality costs to be approximately \$77 million nationally.
- 3.Research demonstrates that medication errors result from the failures of a complex healthcare system and are not the fault of individual healthcare providers.
- 4.Over 17,000 trade and generic products exist, for which many of the names are similar, and many are packaged

similarly.

5.Many factors contribute to a poor understanding by patients about their prescriptions.

6.Improved communication between patients and their health professionals is the most effective means of reducing medication errors.

Resolves that:

1.The Legislature convene a special panel to study causes of medication errors no later than October 1, 2005.

2.The panel recommend improvements, additions, or changes to improve the health care system by reducing medication errors.

3.The panel shall consist of appointees of the Health Committees of the Senate and Assembly.

4.The Speaker of the Assembly shall appoint a member of the faculty of a school of pharmacy; representatives of: the California Pharmacists Association, the California Association of Health Plans, the Pharmaceutical Research and Manufacturers of America, the California Medical Association, the Assembly Republican Caucus; and a consumer representative.

5.The Senate Committee on Rules shall designate the panel's chair and appoint representatives from: the California Retailers Association Chain Drug Committee, the Generic Pharmaceutical Association, the California Society of Hospital Pharmacists, a public health organization, the California Nurses Association, the American Association of Retired People, and the Senate Republican Caucus.

6.The panel shall submit to the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006.

7.The members of the panel shall not receive compensation but shall be reimbursed for travel expenses, and the panel shall be funded by private sources.

FISCAL IMPACT

This is a non-fiscal bill and requires that the panel be funded by private sources.

BACKGROUND AND DISCUSSION

Medical errors

A seminal 1999 report by the Institute of Medicine (IOM), *To Err Is Human: Building a Safer Health System*, effectively launched a national discussion about the seriousness and gravity of medical errors in this country. The report states that between 44,000 and 98,000 people die in hospitals each year as a result of medical errors that could have been prevented. According to the report, "Preventable medical errors in hospitals exceed attributable deaths to such feared threats as motor-vehicle wrecks, breast cancer, and AIDS." The report describes the high and varied types of costs that result from medical errors, totaling between \$17 and \$29 billion per year in hospitals nationwide. Other costs cited include: loss of trust in health care; physical and psychological discomforts for patients; loss of morale and frustration by providers; lost worker productivity; and increased school absences by children.

The IOM study explores the causes of medical errors and concludes that "The majority of medical errors do not result from individual recklessness?errors are caused by faulty systems, processes, and conditions that lead people to make mistakes or fail to prevent them." Within this report, the IOM lays out a comprehensive strategy to reduce preventable medical errors, concluding that the ways to prevent these errors already are known. The strategy includes the following four major goals:

1. Establish a national focus to create leadership, research, tools, and protocols to enhance the knowledge base about safety. Specifically, the IOM recommended that Congress create a "Center for Patient Safety, within the Agency for Healthcare Research and Quality (AHRQ), to set national safety goals, develop a research agenda, and develop, disseminate, and evaluate tools for identifying and analyzing errors, among other tasks.
2. Develop a nationwide public mandatory reporting system and encourage health care organizations and practitioners to develop and participate in voluntary reporting systems. State governments would be required to collect standardized information; hospitals would be required to begin reporting first, and eventually all health care organizations would report.
3. Raise performance standards and expectations for improvements in safety through the actions of oversight organizations, professional groups, and group purchasers of health care. The IOM argues that setting and enforcing explicit performance standards for patient safety through regulatory and related mechanisms, such as

licensing, certification, and accreditation can define minimum performance levels for health professionals. The report states that professional societies should become leaders in encouraging and demanding improvements in patient safety, by setting their own performance standards, communicating with members about safety, and collaborating across disciplines. Public and private purchasers are urged to make safety a prime concern in their contracting decisions.

4. Implement safety systems in health care organizations to ensure safe practices at the delivery level. The report states that, "Safety should be an explicit organizational goal that is demonstrated by strong leadership on the part of clinicians, executives, and governing bodies." This includes: designing jobs and working conditions for safety; standardizing and simplifying equipment, supplies, and processes; and enabling care providers to avoid reliance on memory.

According to the IOM, many actions have occurred to implement these strategies since the issuance of the report in 1999, including:

Congress appropriated \$50 million to the AHQR to: develop and test new technologies; conduct large-scale demonstration projects; and support new and established multidisciplinary teams of researchers in health-care facilities and organizations.

The National Academy for State Health Policy convened leaders from both the executive and legislative branches of the states to discuss approaches to improving patient safety.

The Leapfrog Group, an association of private and public sector group purchasers, unveiled a market-based strategy to improve safety and quality.

The Council on Graduate Medical Education and the National Advisory Council on Nurse Education and Practice held a joint meeting on educational models to ensure patient safety.

In May of 2005, two of the original authors (Lucien Leape, M.D., and Donald Berwick, M.D.) of *To Err is Human* published a follow-up study of progress made in the five years following the IOM report. The authors conclude that, "The groundwork for improving safety has been laid in these past five years but progress is frustratingly slow." They also state that small improvements can be seen at the margins, but the overall national situation remains largely the same. This follow-up report cites the following

barriers to change: creating a culture of safety requires changes that physicians may perceive as threats to their autonomy and authority; fear of malpractice liability leads to an unwillingness to discuss or admit errors; the complexity of the health care industry; a lack of leadership; the lack of measures to gauge progress; and the current reimbursement system that rewards less-safe care. Leape and Berwick argue that the single most important next step is to set and adhere to "strict, ambitious, quantitative, and well-tracked national goals."

Medication errors

The National Coordinating Council for Medication Error Reporting and Prevention is dedicated to preventing medical errors specific to medications. The organization includes the following members: AARP, American Health Care Association, American Hospital Association, American Medical Association, American Nurses Association, American Pharmacists Association, American Society of Health-System Pharmacists, Food and Drug Administration, Generic Pharmaceutical Association, and others. This organization has issued recommendations on reducing medication errors in non-health care settings, reducing errors associated with verbal medication orders, reducing errors related to administration of drugs, error-prone aspects of dispensing medications, labeling and packaging of drugs, and more.

The California Pharmacists Association, the sponsor of the bill, writes in support that "SCR 49 will create a credentialed panel to study the systemic causes of these errors, and make substantive recommendations to reduce them for the protection of the public and for healthcare cost reductions." The California Nurses Association states in support that this panel "will bring together a diverse group of individuals to look at the cause of millions of needless consumer deaths or disabilities due to preventable medication errors." Kaiser Permanente writes in support of the bill that, "This panel would be able to take an informed, independent look at new technologies and different processes that could be used to reduce medication errors."

Prior legislation

SR 44 (Burton, 2004) -- requires the Senate to establish the California Commission on the Fair Administration of Justice to study and review the administration of criminal justice in California, to determine the extent to which that process has failed in the past, resulting in wrongful executions or the wrongful convictions of innocent persons. The Commission must be funded privately and make recommendations to the Legislature and

Governor by December 31, 2007.

SCA 39 (Soto, Chapter 142, Statutes of 2001) -- required the Senate Committee on Public Employment and Retirement to convene a panel to study the funding of pharmacy benefits, co-payments, and other benefit structures of the Public Employees' Medical and Hospital Care Act program, and report back to the Committee by June 1, 2002. The sponsor of SCR 49 states that the SCA 39 process was considered successful by those involved and that valuable recommendations were produced by the panel.

Author's amendment

The author would like to offer an amendment in Committee to add to the panel a representative of the Consumer Healthcare Products Association, to be appointed by the Senate Rules Committee.

POSITIONS

Support: California Pharmacists Association (sponsor)
California Nurses Association
Kaiser Permanente

Oppose: None received.

Attachment 15

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: SB 798

VERSION: AMENDED JUNE 21, 2005

AUTHOR: SIMITIAN

SPONSOR: SIMITIAN

RECOMMENDED POSITION: OPPOSE UNLESS AMENDED

**SUBJECT: HEALTH CARE SERVICE PLANS: PREEXISTING CONDITIONS
PRESCRIPTION DRUGS: COLLECTION**

Existing Law:

Pharmacy Law provides for the licensure and regulation of pharmacists by the board and authorizes a pharmacist to dispense a medication on prescription in a container that meets the requirements of state and federal law and is correctly labeled.

This Bill:

- 1) Authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. (H&S 150004 Added)
- 2) Requires a county that establishes a repository and distribution program would be required to establish procedures for all of the following:
 - a. Establishing eligibility for medically indigent patients who may participate in the program.
 - b. Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.
 - c. Ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacist by ensuring, at a minimum, all of the following:
 - i. That only those drugs that are received and maintained in their unopened, tamper evident packaging are dispensed.
 - ii. That any drugs received have not been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia or the product manufacturer.
 - iii. That any drugs received are dispensed prior to their expiration date.
 - iv. That reasonable methods have been established to ensure that drugs received have not been in the possession of any individual member of the public.
 - v. That a pharmacist may use his or her discretion and best judgment in deciding whether or not to accept any donated drug.
 - vi. That records are kept for at least three years from the date that any drug is received or dispensed, whichever is later, pursuant to this division.

(H&S 150004 Added)

3) Authorizes drug manufacturers to donate excess or surplus unused prescribed medications to programs established by counties. (H&S 15002 Added)

4) States that the following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:

- A prescription drug manufacturer, pharmacy wholesaler, governmental entity, or health facility.
- A pharmacist or health care professional who accepts or dispenses prescription drugs.
- A pharmacy or health facility that employs a health care professional who accepts or can legally dispense prescription drugs.

(H&S 15005 Added)

Comment:

1) Author's Intent. The author's intent is to provide another avenue for low income individuals to obtain prescription.

2) Concerns. Staff is concerned that the current version of the bill is written so broadly that it opens up opportunities for unscrupulous pharmacies to sell donated drugs or introduce counterfeit drugs into the supply. Consequently, staff is recommending numerous amendments to the bill.

3) County by County Approach. Staff is concerned that this bill establishes a framework to offer, on a county by county basis, a program that should be offered statewide, and it vest writing, what should be statewide standard procedures, with individual counties that choose to participate in the program. If enacted this measure would result in a patchwork of individually run programs throughout the state with different eligibility requirements for recipients and different procedures for the pharmacies, drug manufacturers, and health facilities that wish to participate in the program.

4) Other States. Six other states have established drug repository and distribution programs; these are: Oklahoma, Missouri, South Dakota, Wisconsin, Ohio, and Louisiana. An article in the New York Times (Old Pills Find New Uses, May 18, 2005) reports that participation in prescription drug recovery program tends to be low. In Louisiana 12 pharmacies are participation in the statewide program, in Missouri only one clinic has expressed interested in participating, and in Ohio there has been no interest in participating among nursing homes. The article states that the lack of participation is due to due in part because there is little incentive for pharmacies to take on the liability and work required by the program. Additionally it is difficult to insure that returned prescriptions have not been tampered with.

5) Support & Opposition

Support: California Consumer Health Care Council
California Medical Association
City of Palo Alto
Clean Water Action
Santa Clara County Board of Supervisors
Santa Cruz County Health Department
Western Center on Law and Poverty

Opposition: None on file.

AMENDED IN ASSEMBLY JUNE 21, 2005

AMENDED IN SENATE MAY 10, 2005

AMENDED IN SENATE MARCH 29, 2005

SENATE BILL

No. 798

Introduced by Senator Simitian

February 22, 2005

An act to add Division 115 (commencing with Section 150000) to the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 798, as amended, Simitian. Prescription drugs: collection and distribution program.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to dispense a medication on prescription in a container that meets the requirements of state and federal law and is correctly labeled.

This bill would authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. The bill would require a county that elects to establish a repository and distribution program to establish procedures for, at a minimum, (1) establishing eligibility for medically indigent patients who may participate in the program, (2) ensuring that eligible patients are not charged for any medications provided under the program, (3) ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacist, and (4) ensuring the privacy of individuals for whom the medication was originally

6) History.

2005

June 22 Read second time. To third reading.
June 21 Read second time. Amended. To second reading.
June 20 From committee: Do pass as amended. (Ayes 14. Noes 0.)
June 7 Set, first hearing. Held in committee and under submission.
May 26 To Com. on HEALTH.
May 16 In Assembly. Read first time. Held at Desk.
May 16 Read third time. Passed. (Ayes 30. Noes 6. Page 1040.) To Assembly.
May 10 Read second time. Amended. To third reading.
May 9 From committee: Do pass as amended. (Ayes 10. Noes 0. Page 953.)
Apr. 11 Set for hearing May 4.
Mar. 30 Withdrawn from committee. Re-referred to Com. on HEALTH.
Mar. 29 From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 23 Set for hearing April 6.
Mar. 10 To Coms. on B., F. & I. and HEALTH
Feb. 24 From print. May be acted upon on or after March 26.
Feb. 22 Introduced. Read first time. To Com. on RLS. for assignment. To print.

prescribed. The bill would authorize any drug manufacturer legally authorized under federal law to manufacture or sell pharmaceutical drugs, *or a licensed health facility, pharmacy wholesaler, or pharmacy* to donate medications pursuant to these provisions. *Except in cases of bad faith or gross negligence, the bill would prohibit certain people and entities from being subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the bill's provisions.*

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Division 115 (commencing with Section
2 150000) is added to the Health and Safety Code, to read:

3
4 DIVISION 115. SURPLUS MEDICATION COLLECTION
5 AND DISTRIBUTION
6

7 150000. It is the intent of the Legislature in enacting this
8 division to authorize the establishment of a voluntary drug
9 repository and distribution program for the purpose of
10 distributing surplus medications to persons in need of financial
11 assistance to ensure access to necessary pharmaceutical
12 therapies.

13 150002. A health facility licensed under Chapter 2
14 (commencing with Section 1250) of Division 2, *a pharmacy*
15 *wholesaler licensed pursuant to Article 11 (commencing with*
16 *Section 4160) of Chapter 9 of Division 2 of the Business and*
17 *Professions Code*, a pharmacy licensed pursuant to Chapter 9
18 (commencing with Section 4000) of Division 2 of the Business
19 and Professions Code, and a drug manufacturer that is legally
20 authorized under federal law to manufacture and sell
21 pharmaceutical drugs, may donate excess or surplus unused
22 prescribed medications under a program established by a county
23 pursuant to this division.

24 150004. (a) A county may establish, by local ordinance, a
25 repository and distribution program for purposes of this division.

1 (b) A county that elects to establish a repository and
2 distribution program pursuant to this division shall establish
3 procedures for, at a minimum, all of the following:

4 (1) Establishing eligibility for medically indigent patients who
5 may participate in the program.

6 (2) Ensuring that patients eligible for the program shall not be
7 charged for any medications provided under the program.

8 (3) Ensuring proper safety and management of any
9 medications collected by and maintained under the authority of a
10 licensed pharmacist by ensuring, at a minimum, all of the
11 following:

12 (A) That only those drugs that are received and maintained in
13 their unopened, tamper-evident packaging are dispensed.

14 (B) That any drugs received have not been adulterated,
15 misbranded, or stored under conditions contrary to standards set
16 by the United States Pharmacopoeia or the product manufacturer.

17 (C) That any drugs received are dispensed prior to their
18 expiration date.

19 (D) That reasonable methods have been established to ensure
20 that drugs received have not been in the possession of any
21 individual member of the public.

22 (E) That a pharmacist may use his or her discretion and best
23 judgment in deciding whether or not to accept any donated drug.

24 (F) That records are kept for at least three years from the date
25 that any drug is received or dispensed, whichever is later,
26 pursuant to this division.

27 (G) That pharmacists adhere to standard pharmacy practices as
28 required by state and federal law when dispensing all prescription
29 drugs, including narcotics and other controlled substances.

30 (H) That donated drug stock is stored separately from a
31 pharmacy's general supply for inventory, accounting, and
32 inspection purposes.

33 (I) That any county that elects to dispense narcotics and other
34 controlled substances is required to receive public comment from
35 local law enforcement prior to establishing local protocols for
36 packaging, transporting, storing, and distributing narcotics and
37 other controlled substances.

38 (J) That local protocols established pursuant to this act adhere
39 to any applicable requirements established by the California State
40 Board of Pharmacy regarding packaging, transporting, storing,

1 and dispensing all prescription drugs, including narcotics and
2 controlled substances.

3 (K) That county protocols established for packaging,
4 transporting, storing, and dispensing medications that require
5 refrigeration, including, but not limited to, any biological product
6 as defined in Section 351 of the Public Health and Service Act
7 (42 U.S.C. Sec. 262), an intravenously injected drug, or an
8 infused drug, include specific procedures to ensure that these
9 medications are packaged, transported, stored, and dispensed at
10 their appropriate temperatures and according to any applicable
11 standards established by the California State Board of Pharmacy.

12 (L) That, notwithstanding any other provision of law,
13 participating pharmacies adhere to the same procedural drug
14 pedigree requirements for donated drugs as they would for drugs
15 purchased from a wholesaler or directly from a drug
16 manufacturer.

17 (4) Ensuring the privacy of individuals for whom the
18 medication was originally prescribed.

19 *150005. The following persons and entities shall not be*
20 *subject to criminal or civil liability for injury caused when*
21 *donating, accepting, or dispensing prescription drugs in*
22 *compliance with this division:*

23 *(a) A prescription drug manufacturer, pharmacy wholesaler,*
24 *governmental entity, or health facility.*

25 *(b) A pharmacist or health care professional who accepts or*
26 *dispenses prescription drugs.*

27 *(c) A pharmacy or health facility that employs a health care*
28 *professional who accepts or can legally dispense prescription*
29 *drugs.*

30 *150006. The immunities provided in Section 150005 shall not*
31 *apply in cases of bad faith or gross negligence.*

32 *150007. Nothing in this division shall affect disciplinary*
33 *actions taken by licensing and regulatory agencies.*

Attachment 16

AMENDED IN ASSEMBLY JUNE 21, 2005

AMENDED IN SENATE APRIL 28, 2005

AMENDED IN SENATE APRIL 11, 2005

SENATE BILL

No. 380

Introduced by Senator Alquist

February 17, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 380, as amended, Alquist. Drugs: adverse event reporting.

The Sherman Food, Drug and Cosmetics Law provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration of the State Department of Health Services. A violation of these provisions is a crime.

This bill would require a licensed health professional and a health facility to report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration (FDA), using the FDA 3500 Voluntary form developed by the FDA for MedWatch. The bill would prohibit a licensed health professional or health facility that violates this provision from being subject to the existing penalties and remedies of the Sherman Food, Drug and Cosmetics Law or any other provision of law.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) The federal Food and Drug Administration (FDA) operates
4 a voluntary reporting system for adverse drug reactions known as
5 the MedWatch system.

6 (b) The FDA currently estimates that only 10 percent of the
7 adverse drug reactions or events that occur each year are reported
8 to the FDA.

9 (c) Given the prevalence of pharmaceuticals and their use for
10 treatment of hundreds of chronic diseases and conditions, and
11 given recent highly publicized instances of commonly used
12 prescription drugs being taken off the market due to safety
13 concerns that were discovered after the drugs were approved for
14 use, the systematic underreporting of adverse drug events
15 represents a serious public health problem.

16 (d) Requiring licensed health professionals of organizations to
17 report adverse drug events to the FDA would increase the
18 amount of data available to the FDA about adverse drug
19 reactions, thereby enabling the FDA to discern problems with
20 drugs that arise after they are approved and to take action to
21 protect the public health in a more timely manner.

22 SEC. 2. Article 7 (commencing with Section 111657) is
23 added to Chapter 6 of Part 5 of Division 104 of the Health and
24 Safety Code, to read:

25
26 Article 7. Adverse Event Reporting
27

28 111657. (a) A licensed health professional, including, but not
29 limited to, a physician and surgeon, dentist, or pharmacist, and a
30 health facility, including, but not limited to, a hospital or clinic,
31 shall report all suspected serious adverse drug events that are
32 spontaneously discovered or observed in medical practice to
33 MedWatch, the drug safety information and adverse event
34 reporting program operated by the federal Food and Drug
35 Administration.

36 (b) For purposes of this section, serious adverse drug events
37 shall include adverse health outcomes involving patients that
38 result in death, life-threatening conditions, hospitalization,

1 disability, congenital anomaly, or required intervention to
2 prevent permanent impairment or damage.

3 (c) Any health professional or health facility that is required to
4 report an adverse drug event pursuant to this section shall do so
5 using the FDA 3500 Voluntary form developed by the federal
6 Food and Drug Administration for MedWatch.

7 111658. A licensed health professional or health facility that
8 violates any provision of this article shall not be subject to the
9 penalties and remedies outlined in Chapter 8 (commencing with
10 Section 111825) or any other provision of law. *Nothing in this*
11 *section affects otherwise existing duties, rights, or remedies*
12 *under the law.*



CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: SB 380

VERSION: AMENDED APRIL 28, 2005

AUTHOR: ALQUIST

SPONSOR: SENIOR CITIZENS, SO. CAL

RECOMMENDED POSITION: NO POSITION

SUBJECT: DRUGS: ADVERSE EVENT REPORTING

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufactures to report adverse drug reactions.

This Bill:

1) Requires a licensed health professional, (a physician and surgeon, dentist, or pharmacist), and a health facility, (a hospital or clinic), to report all suspected serious adverse drug events that are spontaneous or observed in medical practice to the FDA's MedWatch program.

2) Requires the report to be made using FDA 3500, Voluntary form.

3) Defines a serious adverse drug events as, adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

4) Provides that a person or health facility that violates any provision of the measure would not be subject to penalties and remedies in H&S 111825 or any other provisions in law. (Penalties under H&S 111825 are imprisonment for not more than one year in the county jail or a fine of not more than \$1,000, or both the imprisonment and fine.)

(H&S 111657 Added)

Comment:

1) Author's Intent. The author is concerned that the FDA may not be receiving enough information about adverse drug reactions to make informed decisions to protect the public health.

2) Enforcement. This bill lacks language that would make the bill enforceable. There is no way to know how many adverse drug reactions a health professional observes each year. Consequently this bill would be impossible to enforce. Additionally, it is unclear how each regulatory board would know that an event should have been reported, but wasn't.

3) FDA's MedWatch Program. MedWatch is a voluntary reporting program run by the FDA that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.

Reporting is done on line, by phone, or by submitting the MedWatch 3500 form by mail or fax. The FDA disseminates medical product safety alerts, recalls, withdrawals, and important labeling changes to the medical community and the general public via its web site and the Med Watch E-list.

4) Drugmakers Plans for Voluntary Disclosure on the Internet. Reuters News reported on May 16, 2005 that the pharmaceutical industry plans to launch a global website in September 2005, pooling information on ongoing and completed clinical trials. Additionally, in January 2005, drugmakers in the United States, Europe, and Japan agreed on a voluntary code to publish detailed clinical trials data. Data would be available through a single website with links to company websites and other commercial and government-sponsored websites containing information provided by firms. The voluntary code is backed by Pfizer Inc, GlaxoSmithKline Plc, Merck, AstraZeneca Plc, Novartis AG and Sanofi-Aventis SA.

5) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

AB 71 (Chan) Office of California Drug Safety Watch, would require DHS to 1) establish a central repository of information about the safety and effectiveness of prescription drugs; and 2) disseminate information to health care professionals and consumers through a Web site that would include links to other relevant web-based information that has been professionally reviewed and approved.

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill and will be amended for other purposes.

6) Federal Legislation. On May 4, 2005, Congressman Hinchey introduced H.R. 2090, the Food and Drug Administration Improvement Act of 2005. This bill would: 1) establish within the FDA a Center for Postmarket Drug Safety and Effectiveness to monitor all approved drugs as well as all advertisements and promotions associated with those products; 2) prohibit the FDA from collecting fees paid by companies it regulates and instead, deposit those funds into the general fund of the Treasury; 3) empower the FDA with the authority to mandate that companies conduct post-marketing studies of FDA-approved drugs; and 4) enable the FDA to mandate changes to labels of FDA-approved products if a new risk is discovered. HR 2090 has been referred to the House Committee on Energy and Commerce.

7) Support & Opposition.

Support: American Federation of State, County and Municipal Employees
California Alliance for Retired Americans
California Labor Federation
California Psychological Association
California Public Interest Research Group
Congress of California Seniors
Consumers Union
Greenlining Institute
Health Access California
Protection and Advocacy, Inc.

Opposition: American College of Obstetricians and Gynecologists, Region IX
California Hospital Association
California Medical Association
California Society of Health-System Pharmacists
Kaiser Permanente

8) History.

2005

June 29 From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 7. Noes 0.) Re-referred to Com. on APPR.

June 21 From committee with author's amendments. Read second time. Amended. Re-referred to committee.

June 15 From committee: Do pass, but first be re-referred to Com. on B. & P. (Ayes 9. Noes 4.) Re-referred to Com. on B. & P.

June 7 Set, first hearing. Hearing canceled at the request of author.

May 26 To Coms. on HEALTH and B. & P.

May 2 In Assembly. Read first time. Held at Desk.

May 2 Read third time. Passed. (Ayes 23. Noes 13. Page 867.) To Assembly.

Apr. 28 Read second time. Amended. To third reading.

Apr. 27 From committee: Do pass as amended. (Ayes 9. Noes 2. Page 767.)

Apr. 18 Set for hearing April 25.

Apr. 11 Read second time. Amended. Re-referred to Com. on APPR.

Apr. 7 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 7. Noes 3. Page 411.)

Mar. 14 Set for hearing March 30.

Feb. 24 To Com. on HEALTH.

Feb. 18 From print. May be acted upon on or after March 20.

Feb. 17 Introduced. Read first time. To Com. on RLS. for assignment. To print.

SB 380

As Amended: June 21, 2005

ASSEMBLY COMMITTEE ON BUSINESS AND PROFESSIONS

Gloria Negrete McLeod, Chair
SB 380 (Alquist) -

SENATE VOTE : 23-13

SUBJECT : Drugs: adverse event reporting.

SUMMARY : Requires health care providers to report suspicious serious adverse drug events to the federal Food and Drug Administration (FDA) Specifically, this bill :

- 1) Requires licensed health professionals and health facilities to report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the FDA. Requires such reports to be done using Form FDA 3500 for voluntary reporting.
- 2) Defines serious adverse drug events, for purposes of this bill, to mean adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.
- 3) Prohibits a licensed health professional or health facility that violates this bill from being subject to the penalties and remedies of the Sherman Food, Drug and Cosmetics Law (Sherman Law) or any other provision of law.

EXISTING LAW :

- 1) Establishes the Sherman Law, which provides for the regulation of food, drugs and cosmetics under the administration of the Department of Health Services (DHS). Makes a violation of the Sherman Law a crime.
- 2) Establishes, under federal law, the MedWatch program as a voluntary safety and adverse event reporting system, administered by FDA.

FISCAL EFFECT : Unknown. According to the Senate Appropriations Committee analysis, \$100,000 over two budget years for notification of health care professionals and health facilities about this new requirement and for DHS to investigate a few reporting incidents to see if the appropriate reports are being filed.

COMMENTS :

Purpose of this bill . According to the author, this bill is needed to increase the reporting of adverse drug reactions. Currently, health professionals are only required to report adverse drug reactions on a voluntary basis. The author reports that this results in reporting of only a small percent of the adverse drug reactions that occur. Based on the prevalence of prescription drug use and the recent recall of frequently used drugs, the author believes that under-reporting of adverse reactions is a serious public health problem. The author reports that adverse drug events or reactions (ADRs) result in more than 2.1 million injuries each year and states that studies reported in the Journal of the American Medical Association (JAMA) found that 100,000 Americans die annually of adverse reactions to prescription drugs and that the risk of death for a patient who experiences an ADR is estimated to be nearly twice that of a patient who does not.

Background . With the use of any medication comes the possibility of unintended consequences. These events, when harmful, are often referred to ADRs. According to a 1997 JAMA article, "Adverse Drug Reactions in Hospitalized Patients," an estimated 770,000 people are injured or die each year in hospitals from ADRs. A separate report estimates that ADRs are responsible for up to 140,000 injuries or death in the United States each year. According to the FDA, the estimated cost of morbidity and mortality related to ADRs is more than \$75 billion annually, and ADRs are among the top 10 leading causes of death.

Premarketing trials of drugs frequently do not have a large enough sample of drug recipients to reliably detect important ADRs, which may only occur at the rates of 1 in 10,000 or fewer drug exposures. Premarketing trials also lack the follow-up necessary to detect ADRs widely separated in time from the original use of the drug or delayed consequences associated with long-term drug administration. Taken together, these limitations of premarketing clinical trials mean that FDA approval of a new drug does not exclude the possibility of rare but serious ADRs or common, delayed ADRs. A number of methods have been used to identify previously unknown detrimental outcomes that may be attributable to the use of medications, including post approval spontaneous case reports.

According to an article, "Postmarketing Surveillance and Adverse Drug Reactions," reported in JAMA in 1999, more serious ADRs have been noted first in case reports than any other detection method. One such case reporting system is the MedWatch program that was introduced by the FDA in 1993 to improve the detection of previous unknown serious ADRs. Under MedWatch, health care

professionals are encouraged to voluntarily report serious events suspected to be caused by medications, medical devices, special nutritional products, and other products regulated by the FDA. Serious events are those that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage. (This bill uses the same definition of serious events.) Physicians may report ADRs by telephone, fax, or mail or through the Internet. Despite the importance of physician reports for detecting ADRs, serious adverse events that may represent ADRs are vastly underreported by physicians to either manufacturers or the FDA. According to the FDA, the extent of underreporting is unknown with researchers estimating that as few as less than 1%, to as many as 8-13%, of ADRs being reported. Currently, the FDA receives approximately 250,000 voluntary MedWatch reports annually.

The FDA also has a mandatory ADR reporting process for drug manufacturers who are required to report to the FDA any suspected ADR reports within 15 days of receipt of such a report. In addition, user-facilities such as hospitals and nursing homes are legally required to report suspected medical device-related deaths to both FDA and the manufacturer, if known, and serious injuries to the manufacturer or to FDA, if the manufacturer is unknown.

Support . Supporters argue that this bill protects the health of California consumers by improving the detection of serious side effects of medications that have reached the market. Supporters believe that voluntary reporting of ADRs is inadequate and that mandatory reporting should be required. Supporters point to multiple recalls of medications that have taken place only after many Americans have suffered injury or death from their side effects. Mandatory reporting would provide an earlier warning to the FDA about potentially harmful drugs and allow warning labels or removal from the market to occur sooner, before more people have been harmed. Consumers Union argues that FDA officials have reported that the lack of adequate reporting of adverse drug reactions inhibits the agency's ability to identify dangerous drugs.

Opposition . Opponents argue that this bill would not improve the delivery of health care, that it is often impossible to narrow the cause of an adverse event to a reportable issue, and that virtually all adverse drug events will result in an intervention to prevent permanent impairment or damage. Opponents support continued voluntary, rather than mandatory, reporting.

Related legislation . AB 71 (Chan) would establish the Office of California Drug Safety Watch within DHS to create a central

repository of information about the safety and effectiveness of prescription drugs that are frequently advertised on television. AB 71 passed the Assembly and is pending in the Senate.

Questions and comments . Will the requirement to report serious ADRs result in increased reporting given that this bill prevents the imposition of any penalties for failure to report? Should this bill have a sunset date, allowing its repeal if it fails to significantly increase reporting or otherwise fails to accomplish the author's goal?

REGISTERED SUPPORT / OPPOSITION :

Support

American Federation of State, County and Municipal Employees
California Alliance for Retired Americans
California Labor Federation
California Psychological Association
California Public Interest Research Group
Congress of California Seniors
Consumers Union
Greenlining Institute
Health Access California
Protection and Advocacy, Inc.

Opposition

American College of Obstetricians and Gynecologists, Region IX
California Dental Association
California Hospital Association
California Medical Association
California Society of Health-System Pharmacists
Kaiser Permanente

Analysis Prepared by : Ross Warren / B. & P. / (916) 319-3301

Attachment 17

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AMENDED IN SENATE JUNE 23, 2005
AMENDED IN ASSEMBLY MAY 26, 2005
AMENDED IN ASSEMBLY APRIL 18, 2005
AMENDED IN ASSEMBLY APRIL 7, 2005
AMENDED IN ASSEMBLY FEBRUARY 11, 2005
CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 71

**Introduced by Assembly Members Chan and Frommer
(Coauthors: Assembly Members Bass, Cohn, Evans, Gordon,
Koretz, and Pavley)**

January 3, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 71, as amended, Chan. Pharmaceuticals: adverse drug reactions: Office of California Drug Safety Watch.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would establish the Office of California Drug Safety Watch within the department and would require the office, among other duties, to establish a central repository of information about the safety and effectiveness of prescription drugs ~~frequently advertised on television~~, *that belong to classes of drugs for which there have been*

recently published reports of safety concerns, that have been frequently advertised directly to consumers, and for which there are recently published systematically reviewed evidence-based research that includes research on side effects and safety issues. The bill would require the office to disseminate information to health care professionals and consumers through an Internet Web site; and to request assistance from the University of California and California State University, and to rely on systematically reviewed evidence-based research.

This bill would require the department to impose a fee on any manufacturer of drugs sold in the state, in an amount based on the drug manufacturer's market share of the total amount of drugs sold in the state.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:

3 (a) Since 1997, when the United States Food and Drug
4 Administration (FDA) allowed drug manufacturers to advertise
5 directly to consumers, the amount spent on advertising has risen
6 dramatically.

7 (b) According to the United States General Accounting Office
8 (GAO) report, the pharmaceutical industry spent \$2.7 billion in
9 2001 on direct-to-consumer advertising. A December 6, 2004,
10 New York Times report states that such spending has reached
11 \$3.8 billion.

12 (c) According to the same GAO report, while overall spending
13 on drug promotion was less than spending on research and
14 development (\$19.1 billion versus \$30.3 billion), spending on
15 direct-to-consumer advertising is increasing at a faster rate than
16 overall drug promotion spending or spending on research and
17 development. Between 1997 and 2001, the increase in
18 direct-to-consumer advertising was 145 percent compared to a 59
19 percent increase for research and development.

20 (d) Although the FDA is responsible for postmarket
21 surveillance of prescription drugs, numerous concerns have been
22 raised about the adequacy of these efforts.

1 (e) An unpublished internal FDA study from 2002 revealed
2 that 18 percent of FDA scientists reported being pressured to
3 approve a new drug “despite reservations about the safety,
4 efficacy or quality of the drug.”

5 (f) A 1999 FDA survey and a Kaiser Family Foundation
6 survey both found that more than 50 million people respond to
7 drug advertisements by asking their doctor whether the
8 advertised medications might work for them. At the same time,
9 both surveys showed that almost 60 percent of consumers found
10 the side-effect warnings in these advertisements to be inadequate.

11 (g) Pressure to get new drugs to market, combined with the
12 vast amount of drug marketing undertaken by manufacturers,
13 make it difficult to address a threat once it is identified. Recent
14 studies linking the use of popular, widely promoted prescription
15 drugs to serious public health concerns point to the need for
16 greater oversight to protect the public.

17 (h) *Drugs that are frequently advertised to consumers present*
18 *special safety concerns because direct-to-consumer advertising*
19 *is likely to minimize potential side effects and safety concerns*
20 *and because advertised drugs are likely to be highly utilized by*
21 *Californians.*

22 ~~(h)~~

23 (i) Californians do not have a reliable central repository of
24 information about prescription drug safety and effectiveness.

25 ~~(i)~~

26 (j) California physicians and other prescribers could benefit
27 from a reliable central repository of information about
28 prescription drug safety and effectiveness.

29 ~~(j)~~

30 (k) Various nationally respected sources of clinical
31 information are available as sources for a central repository of
32 information about prescription drug safety and effectiveness.

33 ~~(k)~~

34 (l) Safer and more effective prescription drugs within a class
35 may also be among the less expensive prescription drugs within
36 that class, meaning that a reliable central repository of
37 information about prescription drug safety and effectiveness
38 would create opportunities for prescription drug cost savings.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Office of California Drug Safety Watch

111657. (a) There is hereby established in the State Department of Health Services the Office of California Drug Safety Watch, which shall do all of the following, to provide Californians with information on the safety and effectiveness of prescription drugs:

(1) Establish a central repository of information about the safety and effectiveness of prescription drugs that are frequently advertised on television; *selected pursuant to subdivision (b). The repository shall not include information about any therapeutic class of drugs that is used primarily to treat mental illness.*

(2) Disseminate information to California health care professionals and consumers through an Internet Web site that shall include links to other relevant Web-based information that has been professionally reviewed and approved. *The Internet Web site shall include the following statement: "Many factors enter into selecting the proper drug for individual patients. Before changing any medication, a patient shall consult with his or her treating physician or other prescriber."*

(3) Ensure that the dissemination of information is done in a culturally competent manner and addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available. *When there is no evidence supporting the differential impact of medication among various demographic groups, it shall be noted on the Internet Web site.*

~~(4) In selecting therapeutic classes of drugs about which to develop information, the office shall choose the four most frequently advertised classes of drugs for which there is recently published systemically reviewed evidence-based research.~~

~~(5) Request appropriate units of the University of California and the California State University to provide assistance.~~

~~(6) Rely on systematically reviewed evidence-based research.~~

~~(b) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.~~

1 ***(b) In selecting therapeutic drugs about which to develop***
2 ***information, the office shall only include classes of drugs that***
3 ***have all of the following characteristics:***

4 ***(1) Classes of drugs for which there have been recently***
5 ***published reports of safety concerns.***

6 ***(2) Classes of drugs that have been frequently advertised***
7 ***directly to consumers.***

8 ***(3) Classes of drugs for which there are recently published***
9 ***systemically reviewed evidence-based research that includes***
10 ***research on side effects and safety issues.***

11 ***(c) The office shall request the appropriate units of the***
12 ***University of California and the California State University to***
13 ***provide assistance in implementing this article.***

14 ***(d) The office shall coordinate its activities with other state***
15 ***departments and agencies to avoid unnecessary duplication.***

16 ***(e) The office shall rely on systemically reviewed***
17 ***evidence-based research.***

18 ***(f) The process that the office uses to identify relevant***
19 ***research and standards of clinical evidence shall be transparent***
20 ***and publicly available.***

21 111657.1. For purposes of this article, the following terms
22 have the following meanings:

23 ~~(a) "Evidence-based research" means prescription drug~~
24 ~~research in which the drugs in question have been administered~~
25 ~~to experimental and control groups and the subsequent effect of~~
26 ~~the drugs has been observed through those groups.~~

27 ***(a) "Evidence-based research" means research that is based***
28 ***on clinical evidence, including therapeutic outcomes, and that***
29 ***uses a hierarchy of evidence to evaluate the reliability of the***
30 ***research. In well-conducted research, the hierarchy of evidence,***
31 ***from highest to lowest, is the system review of randomized***
32 ***clinical trials, individual randomized clinical trials, controlled***
33 ***trials, cohort studies, and case control studies.***

34 ***(b) "Systematically reviewed" means review of***
35 ***evidence-based research that uses rigorous, unbiased methods to***
36 ***examine the similarities and differences of results across many***
37 ***individual research studies. The goal of a systematic review is to***
38 ***estimate the comparative effectiveness and safety of health care***
39 ***treatments. A systematic approach to reviewing the evidence***

1 increases the reliability of the results, and the transparency of the
2 procedures.

3 ~~(e) “Most frequently advertised classes of drugs” means the~~
4 ~~therapeutic classes of drugs most frequently advertised on~~
5 ~~television for the six-month period prior to the date the office~~
6 ~~begins compiling the drug safety and effectiveness information~~
7 ~~required by this article. Frequently advertised classes of drugs~~
8 ~~shall not include any therapeutic class that is used primarily to~~
9 ~~treat mental illness.~~

10 111657.2. (a) *There is hereby imposed, pursuant to this*
11 *section, a fee on manufacturers of drugs sold in the state.*

12 (b) (1) *The specific fee to be assessed on a drug manufacturer*
13 *shall be established by the State Department of Health Services,*
14 *to the maximum extent practicable, on the basis of a drug*
15 *manufacturer’s market share of the total amount of drugs sold in*
16 *the state.*

17 (2) *A fee shall not be assessed on a drug manufacturer that*
18 *can demonstrate, as determined by the State Department of*
19 *Health Services, that it does not manufacture drugs that have the*
20 *characteristics described in subdivision (b) of Section 111657.*

21 (c) *The fee shall be assessed and collected annually by the*
22 *State Board of Equalization in accordance with Part 22*
23 *(commencing with Section 43001) of Division 2 of the Revenue*
24 *and Taxation Code. The fees collected shall be deposited in the*
25 *Drug Safety Watch Fund, which is hereby established in the State*
26 *Treasury. Moneys in the fund shall be expended, upon*
27 *appropriation by the Legislature, for the purposes of this article,*
28 *including the costs of the State Board of Equalization for*
29 *collection and administration of fees. All interest earned on the*
30 *moneys that have been deposited into the Drug Safety Watch*
31 *Fund shall be retained in the fund.*

32 (d) *The fees collected pursuant to this section and the earnings*
33 *therefrom shall be used solely for the purposes of implementing*
34 *this article. The department shall not collect fees pursuant to this*
35 *section in excess of the amount reasonably anticipated by the*
36 *department to fully implement this article. The department shall*
37 *not spend more than it collects from the fees, and the earnings*
38 *thereon, in implementing this article.*

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 71

VERSION: AMENDED JUNE 23, 2005

AUTHOR: CHAN et. al.

SPONSOR: CHAN

RECOMMENDED POSITION: NO POSITION

SUBJECT: PHARMACEUTICALS: ADVERSE DRUG REACTIONS: OFFICE OF CALIFORNIA DRUG SAFETY WATCH

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers about adverse drug reactions.

This Bill:

- 1) Establishes the Office of California Drug Safety Watch (office) within the Department of Health Services (DHS). (H&S 111657 Added)
- 2) Requires the office to do all of the following:
 - a. Establish a central repository of information about the safety and effectiveness of prescription drugs; the office would not collect information on drugs that are used primarily to treat mental illness.
 - b. Disseminate information to health care professionals and consumers through an Internet Web site that would include links to other relevant web-based information that has been professionally reviewed and approved. Requires that website to contain the following statement: "Many factors enter into selecting the proper drug for individual patients. Before changing any medication, a patient shall consult with his or her treating physician or other prescriber."
 - c. Assure that the dissemination of information is done in a culturally competent manner and addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available.
 - d. Request units of the University of California and the California State University to provide assistance.
 - e. Rely on systematically reviewed evidence-based research.
 - f. Requires the office to select therapeutic classes of drugs to develop information on, that have 1) been recently published reports of safety concern; 2) been frequently advertised

directly to consumers; and 3) had recently published systemically reviewed evidence-based research that includes research on side effects and safety issues.

(H&S 111657 Added)

3) Requires the office to coordinate its activities with other state departments and agencies to avoid unnecessary duplication. (H&S 111657 Added)

4) Defines the following terms, evidence-based research and systematically reviewed. (H&S 111657.1 Added)

5) Requires DHS to impose a fee on any manufacturer of drugs sold in the state, in an amount based on the drug manufacturer's market share of the total amount of drugs sold in the state. (H&S 111657.2 Added)

6) Establishes the Drug Safety Watch Fund in the State Treasury. (H&S 111657.2 Added)

Comment:

1) Author's Intent. The author is concerned about drug safety and the perceived inability of the Federal government to take action to warn the public about potentially dangerous drugs.

2) Necessity for Bill? The intent of this legislation is to provide Californians with a reliable central repository of information about prescription drugs safety and effectiveness. This type of information is currently available through many sources, including the FDA, the Oregon Drug Effectiveness Review Project (ODERP), Consumers Union [Reports], and the AARP; all of which have Web sites that consumers and healthcare professionals can access for information. Given that reliable information is available, perhaps it would better and less costly for the Administration to direct DHS to establish a Web site with links to information on drug safety, rather than passing legislation that would require to DHS to establish a new program that essentially duplicates what is being done by other entities.

3) Drugmakers Plans for Voluntary Disclosure on the Internet. Reuters News reported on May 16, 2005 that the pharmaceutical industry plans to launch a global website in September 2005, pooling information on ongoing and completed clinical trials. Additionally, in January 2005, drugmakers in the United States, Europe, and Japan agreed on a voluntary code to publish detailed clinical trials data. Data would be available through a single website with links to company websites and other commercial and government-sponsored websites containing information provided by firms. The voluntary code is backed by Pfizer Inc, GlaxoSmithKline Plc, Merck, AstraZeneca Plc, Novartis AG and Sanofi-Aventis SA.

4) Federal Legislation. On May 4, 2005, Congressman Hinchey introduced HR 2090, the Food and Drug Administration Improvement Act of 2005. This bill would: 1) establish within the FDA a Center for Postmarket Drug Safety and Effectiveness to monitor all approved drugs as well as all advertisements and promotions associated with those products; 2) prohibit the FDA from collecting fees paid by companies it regulates and instead, deposit those funds into the general fund of the Treasury; 3) empower the FDA with the authority to mandate that companies conduct post-marketing studies of FDA-approved drugs; and 4) enable the FDA to mandate changes to labels of FDA-approved products if a new risk is discovered. HR 2090 has been referred to the House Committee on Energy and Commerce.

5) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

SB 380 (Alquist) Drugs: Adverse Event Reporting, would require licensed health professionals and a health facilities to report serious adverse drug events that they observe to MedWatch, the FDA's drug safety information and adverse event reporting program. (MedWatch is a voluntary reporting program that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.)

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill that was introduced but not heard in its first committee.

6) History.

2005

June 27	In committee: Set, first hearing. Hearing canceled at the request of author.
June 23	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
June 15	Referred to Com. on HEALTH.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 44. Noes 34. Page 2146.)
May 27	Read second time. To third reading.
May 26	From committee: Amend, and do pass as amended. (Ayes 12. Noes 5.) (May 25). Read second time and amended. Ordered returned to second reading.
April 27	In committee: Set, first hearing. Referred to APPR. suspense file.
Apr. 19	Re-referred to Com. on APPR.
Apr. 18	Read second time and amended.
Apr. 14	From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 9. Noes 4.) (April 12).
Apr. 11	Re-referred to Com. on HEALTH.
Apr. 7	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Feb. 15	Re-referred to Com. on HEALTH.
Feb. 11	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Com. on HEALTH.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

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AB 71

As Amended May 26, 2005

ASSEMBLY THIRD READING

Majority vote

HEALTH 9-4 APPROPRIATIONS 12-5

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|Ayes:|Chan, Berg, Cohn,      |Ayes:|Chu, Bass, Berg, Mullin, |
| |Frommer,                  | |Karnette, Klehs, Leno,   |
| |De La Torre, Jones,      | |Nation, Oropeza,        |
| |Montanez, Negrete McLeod,| |Ridley-Thomas, Saldana, |
| |Ridley-Thomas            | |Yee                      |
| |                          | |                          |
|-----+-----+-----+-----|
|Nays:|Aghazarian, Nakanishi, |Nays:|Sharon Runner, Emmerson, |
| |Richman, Strickland      | |Haynes, Nakanishi,      |
| |                          | |Walters                  |
|-----+-----+-----+-----|
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SUMMARY : Establishes the Office of California Drug Safety Watch (Office) within the Department of Health Services (DHS) to create a central repository of information about the safety and effectiveness of prescription drugs that are frequently advertised on television. Specifically, this bill:

1) Establishes the Office of California in DHS to do all of the following:

- a) Establish a central repository of information about the safety and effectiveness of prescription drugs that are frequently advertised on television;
- b) Disseminate information to health care professionals and consumers through an Internet Web site which shall include links to other relevant web-based information that has been professionally reviewed and approved;
- c) Ensure that the dissemination of information is done in a culturally competent manner, and that addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available;
- d) In selecting therapeutic classes of drugs about which to develop information, choose the four most frequently advertised classes of drugs for which there is recently published systematically reviewed evidence-based research;

- e) Request units of the University of California and the California State University to provide assistance; and,
 - f) Rely on systematically reviewed evidence-based research.
- 2) Requires the Office to coordinate its activities with other state departments and agencies to avoid unnecessary duplication.
- 3) Defines the following:
- a) "Evidence-based research" means prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups; and,
 - b) "Systematically reviewed" means review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to estimate the comparative effectiveness and safety of healthcare treatments. A systematic approach to reviewing the evidence increases the reliability of the results, and the transparency of the procedures.
 - c) "Most frequently advertised classes of drugs" means the therapeutic classes of drugs most frequently advertised on television for the six-month period immediately prior to the date the Office begins compiling the drug safety and effectiveness information required by this bill. Frequently advertised classes of drugs shall not include any therapeutic class that is used primarily to treat mental illness.

EXISTING LAW :

- 1) Regulates the packaging, labeling and advertising of food, drugs, and cosmetics under the administration of DHS.
- 2) Creates in the federal government the Food and Drug Administration (FDA) to regulate prescription drugs.

FISCAL EFFECT : According to the Assembly Appropriations Committee:

- 1) On-going annual General Fund (GF) personnel costs of \$240,000 for staff in the Office.
- 2) GF costs of approximately \$205,000 for the acquisition of journal articles, translation, and field testing of translated

materials in a culturally competent manner.

COMMENTS : To highlight the importance of this bill, the author points to the withdrawal of Vioxx and Celebrex in November and December 2004 from the market because of the risks of heart attack associated with taking these drugs. On April 7, 2005, FDA asked Pfizer to withdraw Bextra from the market because it increases the risk of heart attacks, stroke and skin reactions. Like Vioxx and Celebrex, Bextra is a cox-2 inhibitor. These events created great insecurities among consumers. The author points out that if there is a single repository of information for the safety and effectiveness of drugs, consumers would have more information on the safety and effectiveness of prescription drugs they are taking and would be encouraged to discuss such information with their physicians.

The pull-out of Vioxx and Celebrex and most recently Bextra from the market because of adverse drug reactions has changed the landscape on how consumers view drugs and associated risks. A 2005 Kaiser Family Foundation survey found that 66% of adults closely followed news stories about Vioxx and Celebrex in December 2004 and a large majority (80%) felt "somewhat" confident about the safety of prescription drugs sold in the United States. The same survey indicated that a vast majority of adults (90%) have seen or heard advertisements for prescription drugs but only 18% of consumers now believe pharmaceutical ads can be trusted "most of the time." This is a significant drop because in 1997 one-third of those surveyed indicated ads could be trusted most of the time. The importance of these drug advertisements to delivering the safety or risks of drugs has caught the attention of FDA when it announced that it would be more aggressive in monitoring drug advertisements so as to balance the presentation of the benefits and risks of particular drugs.

Supporters indicate that prescription drug safety is a serious concern among Californians. Peer-reviewed and scientifically based studies would provide additional and valuable information to physicians, surgeons and patients. The California Medical Association in support notes the importance of this information while emphasizing the need for patients to consult their physicians before discontinuing any prescribed medications.

Letters received in opposition appear to address the February 11, 2005, version of this bill, which would have required DHS to establish a toll-free telephone number to receive reports of adverse drug reactions, establish a Web site with adverse drug reaction information, maintain a database and act as a liaison with the FDA. Opponents claim that FDA's Medwatch, which allows reporting of adverse drug reactions, provides sufficient protection to the public. It is unclear whether they are still

opposed to this bill in its most recently amended form.

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